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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,799	12/11/2003	Barton D. Gaskins	105916.167US1	5878
9629 7590 11/14/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER				
HANDY, DWAYNE K				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/732,799

Applicant(s)

GASKINS ET AL.

Examiner

DWAYNE K. HANDY

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8, 10, 11, 14, 15, 20 and 23-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10, 11, 14, 15, 20 and 23-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "said material" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6-8, 10, 11, 14, 15, 20, 23, 29-31, 35-37, 40, 41, 45, 46 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al. (3,801,280). Shah teaches a device for performing dissolution tests. The device is best shown in Figures 1 and 2 and described in columns 4-6. The device includes a jacketed container (1) with closed bottom and open top, a lid (4) with multiple ports (sleeve 34 and pipe 42), a

filter tube assembly (8) disposed within the first port, and a pump (41) connected by tubes to the ports. Shah teaches filter pore size of 1 micron in column 4, line 63.

5. Claims 1, 6-8, 10, 11, 14, 15, 20, 23, 29-32, 35-37, 40-42, 45, 46 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Bischoff et al. (3,802,272). Bischoff teaches a device for performing dissolution tests. The device is best shown in Figures 1 and 4 and described in columns 3-4. The device includes a container (10) with closed bottom and open top, a cover (82) with multiple ports (sleeve 34 and pipe 42), a filter tube assembly (11) disposed within the first port, and a pump (27) connected by various air driven valves and lines to the ports. Bischoff teaches filter pore size of 44 micron (325 mesh) and polyester mesh in column 4, lines 58-62.

Inventorship

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 24-26, 33, 34, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (3,801,280) or Bischoff et al. (3,802,272). Shah or Bischoff teaches every element of claims 33, 34, 43 and 44 except for the filter size range and container volume. Both Shah and Bischoff are silent as to container sizes and both references teach filter sizes that are below the ranges in the instant claims. The Examiner takes the position that the only difference between the prior art and claimed device elements - the container volume and filter size range - is a recitation of relative dimensions and the prior art would not perform differently. See MPEP 2144.04, Section IV, A. "Changes in Size/Proportion" In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the

prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

9. Claims 28 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (3,801,280) or Bischoff et al. (3,802,272) in view of Mills et al. (6,613,278). Shah or Bischoff teaches every element of claims 28 and 39 except for a sonicator. Shah teaches magnetic stirring and Bischoff does not teach a mixing element. Mills teaches a device used in the demineralization of bone. The device includes a sonicator for mixing (column 7, lines 41-50). Mills teaches that a sonicator provides sonic energy that accelerates solution interpenetration of a porous matrix (column 9, lines 39-55) without gross structural damage (column 7, lines 41-50). It would have been obvious to one of ordinary skill in the art to combine the sonicator mixer from Mills with the device of Shah or Bischoff. Shah and Bischoff teach dissolution testing devices. The use of a mixing element that accelerates matrix penetration without damaging the materials being mixed would provide ideal mixing characteristics in a system that analyzes the dissolution of a porous matrix.

10. Claims 27 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bischoff et al. (3,802,272) in view of Slavazza et al. (6,320,025). Bischoff teaches every element of claims 27 and 38 except for a shaker. Bischoff does not teach a

mixing element. Slavazza teaches a polymer synthesis reactor. The reactor includes a mixing means that may be "a rocking, shaking or swirling device" for mixing the contents of the reactor. It would have been obvious to one of ordinary skill in the art to combine the "rocking, shaking or swirling device" from Slavazza to the device of Bischoff in order to mix the contents of the dissolution chamber.

11. Claims 3-5 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (3,801,280) or Bischoff et al. (3,802,272) in view of Juranas et al. (5,711,917). Shah or Bischoff teaches every element of claims 3-5 and 47 except for the frit element on the second port. Juranas teaches a laboratory reactor apparatus. The apparatus is best shown in Figures 1-3, 6, 7 and 9. The apparatus includes a suction tube (50) secured by an O-ring for the removal of chemicals from the reactor (12). The tube includes a frit for filtering out unwanted solids during compound removal (column 4, lines 29-31). It would have been obvious to one of ordinary skill in the art to combine the tube frit and O-ring from Juranas with the device of Shah or Bischoff. Shah and Bischoff provide a second port for the addition and/or removal of materials from their containers but do not provide a frit for the second port. One would add the frit in order to filter out unwanted solid components as in Juranas. One would use an O-ring to secure the port in order to prevent leakage.

Response to Arguments

12. Applicant's amending of claims 1 and 20 to include a container having a closed bottom and open top as suggested by the Examiner is sufficient to overcome the previous rejection under Simpson in view of Slavazza. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shah and Bischoff.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/Dwayne K Handy/
Examiner, Art Unit 1797
November 9, 2008